

NADA Number: 141-188	
Trade Name	Marquis® Antiprotozoal Oral Paste
Sponsor	Merial, Inc.
Ingredients	Ponazuril
Species	EQUIDS (Horse, not for meat production)
Routes of Administration	Per Os
Dosage Form	Paste
Dispensing Status	RX
Patent Number (Expiration Date)	5883095 (No Expiration Date)
Exclusivity	This supplemental approval for Marquis® Oral Paste qualifies for THREE years of marketing exclusivity under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act because the supplemental application included a study of safety and effectiveness. This exclusivity begins as of the date of our approval letter and only applies to the revised dosage regimen to include a loading dose (Expires 5/21/2018).
Dosage Amount, Indications & Limitations	<p>520.1855 Ponazuril.</p> <p>Specifications: Each gram of paste contains 150 milligrams (mg) ponazuril.</p> <p>Horses</p> <p>Amount: Administer at a dose of 15 mg/kg (6.81 mg/lb) body weight as a loading dose for the first dose only. The loading dose is followed by a maintenance dose of 5 mg/kg (2.27 mg/lb) body weight once daily for a period of 27 additional days.</p> <p>Indications: For the treatment of equine protozoal myeloencephalitis (EPM) caused by Sarcocystis neurona.</p> <p>Limitations: Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.</p>